

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

2007 DEC 21 P 4:38

NEW ENGLAND CARPENTERS HEALTH  
BENEFITS FUND; PIRELLI ARMSTRONG RETIREE  
MEDICAL BENEFITS TRUST; TEAMSTERS HEALTH  
& WELFARE FUND OF PHILADELPHIA AND  
VICINITY; PHILADELPHIA FEDERATION OF  
TEACHERS HEALTH AND WELFARE FUND;  
DISTRICT COUNCIL 37, AFSCME-HEALTH &  
SECURITY PLAN; JUNE SWAN; BERNARD GORTER,  
SHELLY CAMPBELL and CONSTANCE JORDAN,

Plaintiffs,

v.

FIRST DATABANK, INC., a Missouri Corporation; and  
McKESSON CORPORATION, a Delaware Corporation,

Defendants.

U.S. DISTRICT COURT  
DISTRICT OF MASS.

CIVIL ACTION  
NO. 1:05 – CV-11148-PBS

**DECLARATION OF THOMAS CLARK**

I hereby declare, pursuant to 28 U.S.C. § 1746, the following:

1. I submit this Declaration to provide this Court with certain information regarding the services provided by long term care pharmacies and the adverse impact that the Proposed Settlements will have on the quality of those services if they are implemented.

2. I am licensed to practice pharmacy by the state of Illinois. I serve as Director of Policy and Advocacy for the American Society of Consultant Pharmacists ( “ASCP”), a professional society of consultant and senior care pharmacists that is seeking to intervene in order to oppose the proposed settlements between defendants First Data Bank ( “FDB”) and Medi-Span and the

conditionally certified settlement class (“plaintiffs”) in the above-captioned case (the “Proposed Settlements”). I make this declaration based on personal knowledge and, where indicated, on information and belief obtained in my capacity as an employee of ASCP.

3. I have been employed by ASCP for thirteen years, first as Director of Professional Affairs and now as Director of Policy and Advocacy. Prior to my employment at ASCP, I was the Vice President of Consulting for Pharmacy Corporation of America, a long-term care pharmacy providing prescriptions drugs and medication therapy to facilities such as nursing homes and state institutions. Prior to that, I served as the director of a hospital pharmacy in Illinois.

4. I received a Bachelor of Science degree in Pharmacy from the University Of Illinois College Of Pharmacy in Chicago, Illinois and a Master of Health Science degree from Mississippi College in Clinton, Mississippi.

#### ASCP

5. Founded in 1969, ASCP is an international trade association of over 6,000 pharmacists who manage and improve drug therapy and the quality of life for geriatric patients and other individuals residing in a variety of long-term care (“LTC”) environments, including nursing facilities, subacute care and assisted living facilities, psychiatric hospitals, hospice programs, and home and community-based care. ASCP represents pharmacists who work in and/or own such LTC pharmacies throughout the United States.

6. ASCP’s member pharmacists are directly involved in the distribution and monitoring of prescription medications to LTC patients, particularly federal health care program beneficiaries, including more than 1 million elderly beneficiaries in the new “Part D” Medicare Prescription Drug Program (“Part D”).

**LTC PHARMACY**

7. In general, it is cost-prohibitive for nursing homes and other LTC facilities to own and operate their own in-house pharmacies. Thus, almost all nursing homes and other LTC facilities contract with an LTC pharmacy to provide specialized prescription drug and medication therapy services to nursing home residents. LTC pharmacies are most often specially designed to serve LTC facilities, and are not open to the general public and do not maintain any retail operations.

8. The services provided by LTC pharmacies differ markedly from those provided by a typical retail pharmacy in ways that range from the manner of dispensing and delivery to the degree of involvement with a specific patient's care. The pharmacies owned and operated by ASCP's members provide "24/7" pharmacy and delivery services to nursing homes 365 days a year, ensuring timely bedside access to medications, as compared to a typical retail pharmacy where patients must go to pick up drugs. This round-the-clock service ensures that patients needing immediate changes in drug regimens such as complex intravenous compounds receive the necessary medicine no matter what the time of day, avoiding both patient discomfort and the increased cost of hospitalization often brought on by acute situations. LTC pharmacies also provide specialized packaging to reduce medication errors and help ensure that the right patient gets the correct dose of medication at the right time.

9. Further, ASCP's member pharmacists and their pharmacies are essential players on a patient's healthcare team, providing monitoring, review, and consulting services in addition to dispensing drugs to patients in LTC facilities. Among other things, they conduct drug regimen review above and beyond the statutory nursing home requirements, which involves specialized expertise in geriatric drug therapy to help ensure clinical appropriateness of drug therapy for the resident and preempt harmful medication interactions and errors. Moreover, LTC pharmacists are

called upon to consult with treating physicians, counsel patients regarding pain management, and provide nutrition assessment and support.

10. LTC pharmacies are also unique in that they dispense the drugs to the resident and then collect payment from the appropriate source (whereas a retail customer unable to pay for a drug at the drug store counter simply does not receive the drug). Because nursing home and other LTC residents are generally too elderly and/or infirm to go without their medication, LTC pharmacies generally operate on the premise, “dispense first, address payment later.”

11. The critical role LTC pharmacy plays in the quality of nursing home care is particularly important because today’s nursing home residents tend to be older (average age of 83) and sicker (averaging three or more concurrent illnesses) than was the case even a decade ago and, correspondingly, have far greater medication needs (typically eight or more simultaneous prescriptions) than either a typical elderly person or a typical non-elderly Medicaid beneficiary. These patients need the time and attention provided by ASCP’s members not only because of the fragile state of their health but also because they consume a far greater percentage of prescriptions than the typical American consumer.

#### **The Unique Significance of AWP to LTC Pharmacy Pricing**

12. Prior to January 1, 2006, a substantial majority (approximately 70%) of the LTC pharmacy prescriptions dispensed to the more than 1.6 million Americans residing in nursing homes and other LTC facilities were reimbursed through Medicaid, almost universally using an “AWP minus x%” benchmark price, plus a dispensing fee. During this period, the single largest payors for nursing home residents’ prescription drugs were state Medicaid programs.

13. The dispensing fee, originally designed by Medicaid to cover the additional costs of servicing LTC pharmacies’ frail and elderly patients (*see* 42 C.F.R. § 50.504), was typically

between \$3.50 and \$6.00. It was widely known and recognized, however, that the dispensing fee was inadequate to cover actual dispensing costs (reported by one 2002 industry survey to be \$11.32 (*see* [www.ltcpa.org/pdf/BDO.pdf](http://www.ltcpa.org/pdf/BDO.pdf))). As such, the drug price reimbursement component of the pricing formula (i.e., AWP minus x%) was relied upon by both Medicaid and service providers to offset the inadequate dispensing fee component.

14. Together, the reimbursement amount for drug ingredient costs (AWP minus x%), together with the dispensing fee, achieved a largely market-driven reimbursement rate for prescription drugs provided to LTC patients.

15. On January 1, 2006, the pharmaceutical marketplace experienced a fundamental structural shift with the implementation of Medicare Part D. Millions of seniors, including virtually all nursing home residents, began to receive their drug benefits through newly-created private entities known as Part D Prescription Drug Plans (“PDPs”). Thus, for a significant number of Americans, including over 1 million nursing home residents, PDPs have replaced the third party payor (“TPP”) pharmacy benefit providers – whether Medicaid or private insurance – that had served patients prior to 2006.

16. As of January 1, 2006, many of the pharmacies owned by ASCP members and many of the other smaller LTC pharmacies are reimbursed for the vast majority of customers they serve by either (1) the newly-created PDPs participating in Part D, (2) state Medicaid programs, or (3) the LTC facilities themselves, for residents covered by Medicare Part A.

17. Notably, the first category of payors did not exist prior to 2005 or pay for a single prescription until January 1, 2006,<sup>1</sup> while the second category is, I am informed, specifically excluded

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<sup>1</sup> The PDPs entered into contracts with LTC and other pharmacies in mid-to-late 2005. I am informed that the original complaint in this action was filed on June 2, 2005, well before most of this PDP contracting activity took place.

from the putative settlement class in this case (along with all other governmental entities that purchased the drugs at issue during the class period).

18. Medicaid programs and the majority of nursing homes today also continue to reimburse LTC pharmacies based on a discount to the FDB-reported AWP price (AWP-x%), plus a dispensing fee intended to cover a portion of the costs of specialized packaging, delivery, and administrative services. The existing “AWP-x%” reimbursement rates, particularly for the Part D Program that comprises such a large share of LTC pharmacy’s business, have been reached through arm’s-length contract negotiations between pharmacies and Medicare PDPs or LTC facilities (or, in the case of Medicaid for non-Medicare patients, through statutory or rulemaking change).<sup>2</sup> The PDP rates in particular are the product of market negotiations, and have resulted in significant price discounts to consumers and other TPPs that are believed to be consistently below private insurer TPP rates. *See, e.g.,* Center for Medicare and Medicaid Services, Fact Sheet, *Large Negotiated Price Discounts Continue in Medicare Part D* (June 20, 2006).<sup>3</sup> These negotiated or imposed rates are the product of efficient market conduct and have resulted in significant price discounts to consumers and other TPPs.

#### **Potential Impact of the Proposed Settlement on LTC Pharmacies**

19. Unlike some retail pharmacies, which can depend to some degree upon revenues generated by the “front end” sale of non-pharmacy goods (toiletries, over-the-counter products, food, greeting cards, etc.) to meet their bottom line, LTC pharmacies focus

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<sup>2</sup> I am informed that, as a practical matter, some of the smaller pharmacies owned or worked in by ASCP members had little or no ability to negotiate these contracts, but were offered contracts by the PDPs on a “take it or leave it” basis.

<sup>3</sup> Available at <http://www.cms.gov/apps/media/press/release.asp?counter=1885>.

exclusively on the provision of highly specialized pharmacy services and have no other sources of revenue. In an environment in which the increased cost of health care services already produces very narrow profit margins, with no retail or other revenue to soften the blow, smaller LTC pharmacy providers may be forced not only to cut services, but to simply close their doors altogether if the AWP reduction contemplated by the Proposed Settlement goes into effect.

20. At greatest risk are the smaller community LTC pharmacies throughout the country that (a) do not serve large numbers of institutions, (b) have limited reserves, and (c) do not have the economic stability and support of a national level company.

21. Margins for these smaller LTC pharmacies are typically slim. The Proposed Settlement's contemplated reduction of AWP would directly undermine, and further reduce by 4%, their already reduced reimbursement rates, dropping them to sub-market levels and eliminating their profit margin or swinging them to a loss.<sup>4</sup>

22. In the end, the forced reduction of AWP contemplated by the Proposed Settlement may well put some of these smaller LTC pharmacies out of business altogether.

23. Thus, arguably the most essential ASCP members to consider are these small practitioners who operate out of community-level pharmacies. If they are forced to close their doors, this will ultimately harm not only ASCP member pharmacists, but the end consumers, *i.e.*, the frail and elderly nursing home residents whose interests plaintiffs purport to represent.

24. Given the direct, adverse impact that the Proposed Settlement is likely to have on ASCP members and their patients as detailed above, I respectfully submit that ASCP should

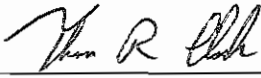
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<sup>4</sup> While certain PDP contracts contain so-called "price adjustment" provisions that would mitigate or negate the effects of the forced reduction in AWP contemplated by the Proposed Settlement, such provisions are not the norm, especially for smaller LTC pharmacies.

be permitted to intervene to oppose final approval of the Proposed Settlement.

I hereby declare, under penalty of perjury, that the foregoing is true and correct to the best of my knowledge.

Dated December 19, 2007



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